

## Remarks

### The claimed invention

In one embodiment, the present invention is a method of assembling a tissue engineered construct, comprising transfecting a plurality of mammalian cells with a gene for a growth factor, and seeding the transfected cells onto a biocompatible matrix comprising a first biocompatible material and a second biocompatible material, wherein the second biocompatible material is selected from one or more of cell adhesion molecules, integrins, cell adhesion sequences, laminin, fibronectin, agar, agarose, collagen, glycosaminoglycans, poly(vinyl alcohol), amino acids, and polymers of amino acids (Claim 10). Claim 10 has been rewritten in independent form to include the recitations of claim 1. Applicant submits that none of the language added to claim 10 narrows the scope of the claim.

### The prior art

Breitbart discloses a method of enhancing and/or increasing the efficiency of tissue repair, particularly bone and cartilage repair, using genetically engineered cells (Col. 3, lines 32-34). The method involves transfecting isolated cells with a gene encoding a growth factor for the particular cell type to be repaired (Col. 3, lines 34-37). The transfected cells may be seeded onto a matrix for implantation to repair a defect and may be cultured on the matrix prior to implantation (Col. 8, lines 35-38). The matrix material may be a synthetic, biocompatible and/or biodegradable polymer (Col. 8, lines 39-42), such as PLA, PGA or PLGA (Col. 8, lines 62-65), or a natural polymer, such as collagen (Col. 9, lines 10-14). Breitbart does not teach that any of these materials may be used to form a matrix in combination with one or more of cell adhesion molecules, integrins, cell adhesion sequences, basement membrane components, laminin, fibronectin, agar, agarose, collagen, glycosaminoglycans, poly(vinyl alcohol), amino acids, and polymers of amino acids. Breitbart does not disclose that hepatocytes, Islet cells or endothelial cells may be transfected with a gene for a growth factor.

Naughton discloses a three-dimensional cell culture system which can be used to culture a variety of different cells and tissues *in vitro* for prolonged periods of time. Naughton discloses that the culture system may include a three-dimensional support produced from, for example, nylon (column 8, line 33). Naughton does not disclose that the materials used to produce the

support may be used in combination with one or more of cell adhesion molecules, integrins, cell adhesion sequences, basement membrane components, laminin, fibronectin, agar, agarose, collagen, glycosaminoglycans, poly(vinyl alcohol), amino acids, and polymers of amino acids.

#### Rejections under 35 U.S.C. § 112

Claims 1-2, 4-21, 43-45, and 47 stand rejected under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement. Applicant respectfully disagrees. Nonetheless, Applicant has amended the claims to recite specific materials that promote cell adhesion. These amendments are supported by the specification at page 11, lines 16-23 and page 6, lines 4-5.

Claim 10 stands rejected under 35 U.S.C. 112, second paragraph. Applicant respectfully disagrees. Nonetheless, claim 10 has been amended to remove the language objected to by the Examiner.

Applicant submits that all the pending claims meet the requirements of 35 U.S.C. 112.

#### Rejections under 35 U.S.C. § 102

Claims 1, 2, 4-21, 43-45, and 47 stand rejected under 35 U.S.C. 102 as being anticipated by Breitbart. Applicant respectfully disagrees. Applicant submits that Breitbart fails to disclose a method including seeding transfected cells on a matrix having first and second materials, wherein the second material includes one or more of cell adhesion molecules, integrins, cell adhesion sequences, basement membrane components, laminin, fibronectin, agar, agarose, collagen, glycosaminoglycans, poly(vinyl alcohol), amino acids, and polymers of amino acids, as recited by claim 10. While Breitbart discloses the use of collagen, he fails to disclose the combination of collagen with a second material to form a matrix. Applicant submits that claims 2, 4-21, 43-45, and 47 are patentable in view of Breitbart.

#### Rejections under 35 U.S.C. § 103

Claims 48-50 and 52 stand rejected under 35 U.S.C. 103 as being obvious over Breitbart in view of Naughton. Applicant respectfully disagrees. Applicant submits that Naughton fails to remedy the failure of Breitbart to teach transfected cells seeded on a matrix having first and second materials, wherein the second material is selected from one or more of cell adhesion

molecules, cell adhesion sequences, integrins, basement membrane components, laminin, fibronectin, agar, agarose, collagen, glycosaminoglycans, poly(vinyl alcohol), amino acids, and polymers of amino acids, as recited by claim 48. Applicant submits that claims 48-50 and 52 are patentable in view of Breitbart and Naughton, whether considered separately or in combination.

Requirement for Restriction

Applicant acknowledges the withdrawal of claims 46 and 51.

A petition for extension of time and the appropriate fee are enclosed herewith. Please charge any fees associated with this filing, or apply any credits, to our Deposit Account No. 03-1721.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Valarie B. Rosen", is written over a horizontal line.

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